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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/441,061	11/16/99	ENDI	J P564-9035

HM12/0927
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EXAMINER	
DECLOUX, A	
ART UNIT	PAPER NUMBER
1644	4

DATE MAILED: 09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/441,061	Endl et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 46-79 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 46-79 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Detailed Action

1. A restriction is required under 35 USC 121 between one of the following groups:

I-XXIII. Claims 46-58, drawn to a complex comprising a peptide derived from glutamic acid decarboxylase, wherein said peptide comprises at least 6 amino acids of an amino acid sequence of SEQ ID NO:2, or SEQ ID NO:3, or one of SEQ ID NO:s 19-39, respectively, a pharmaceutical composition thereof, further comprising an accessory component, classified in Class 530, subclasses 324-329,

XXIV-XLVI. Claims 59-61, drawn to a method of treating or preventing an autoimmune disease or diabetes, or causing an immune response or immune tolerance in a patient comprising administering a complex comprising a peptide derived from glutamic acid decarboxylase, wherein said peptide comprises at least 6 amino acids of an amino acid sequence of SEQ ID NO:2, or SEQ ID NO:3, or one of SEQ ID NO:s 19-39, respectively, classified in Class 514, subclasses 12-17,

XLVII-LXX. Claims 62-76, drawn to an oligomerized peptide, peptide derivative/MHC molecule or MHC molecule derivative complex, wherein said peptide or peptide derivative comprises a peptide of at least 6 amino acids of an amino acid sequence of SEQ ID NO:2, or SEQ ID NO:3, or one of SEQ ID NO:s 19-39, respectively, a pharmaceutical composition thereof, further comprising an accessory component, classified in Class 530, subclass 300,

LXXI-XCIV. Claims 77-79, drawn to a method of treating or preventing an autoimmune disease or diabetes or causing an immune response or immune tolerance in a patient comprising administering an oligomerized peptide, peptide derivative/MHC molecule or MHC molecule derivative complex, wherein said peptide or peptide derivative comprises a peptide of at least 6 amino acids of an amino acid sequence of SEQ ID NO:2, or SEQ ID NO:3, or one of SEQ ID NO:s 19-39, respectively, a pharmaceutical composition thereof, further comprising a cytokine, surface antigen B7, or both, classified in Class 424, subclass 184,

Note: Each group will be examined only to the extent of the elected invention.

The inventions are distinct, each from the other because:

2. Groups XXIV-XLVI and LXXI-XCIV are unique methods. Though the endpoints of the groups are the same, the ingredients are distinct because each administered peptide or complex is distinct. Therefore, Groups XXIV-XLVI and LXXI-XCIV are patentably distinct, each from the other.

3. Groups I-XXIII and XLVII-LXX are unique products. They differ with respect to their physicochemical properties and are therefore patentably distinct.

4. Groups I-XXIII and XXIV-XLVI are related as product and process of use as are

Groups XLVII-LXX and LXXI-XCIV. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the peptides and peptide/MHC complexes can be used as an immunogen in a method of producing monoclonal antibodies.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

6. Regardless of which invention is elected, the applicant is further required under 35 U.S.C. 121:

A) To elect a product or a method comprising a **specific** MHC molecule such as DR3 or DR4 as recited in claim 46, and to elect a **specific** MHC subtype, such as one recited in claim 47 ,

B) To elect a product or a method comprising a **specific** accessory stimulating component, such as a cytokine recited in claim 58. If a cytokine is elected, the applicant is further required to elect a specific cytokine, such as IL-2 as disclosed in the instant specification.

7. If any one of Groups XLVII-XCIV is chosen, applicant is further required to:

A) To elect a product or a method comprising a MHC/peptide complex wherein the two MHC molecules are either **directly** or **indirectly** linked, such as recited in claim 62.

8. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably

distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. The following claim(s) are generic: claims 46-79.

12. The species are distinct each from the other for the following reasons:
The recited peptides, MHC/peptide complexes and accessory molecules each have a distinct sequence and structure, as well as biophysical properties.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Papers related to this application may be submitted to Technology Center 1600

by facsimile transmission. Papers **(other than elections)** should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
September 27, 2001

Patrick J. Nolan
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PRIMARY EXAMINER
9/26/01